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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,517	10/28/2003	James Clement Bishop	01051	5391
35467 7590 04/29/2008 BIOMERIEUX, INC. PATENT DEPARTMENT 100 RODOLPHE STREET DURHAM, NC 27712				
EXAMINER LEVKOVICH, NATALIA A				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
04/29/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/695,517

## Applicant(s)

BISHOP ET AL.

## Examiner

NATALIA LEVKOVICH

## Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendments and remarks filed 01/10/2008 have been acknowledged.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Drawings***

3. The drawings remain objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims, as well as any structural detail that is essential for a proper understanding of the disclosed invention. Therefore, the spring-loaded member engaging with the test sample device when the cutting element is moved in the deployed position, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

### ***Claim Rejections - 35 USC § 112***

4. Claims 1-4 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, as amended, recites sample testing instrument comprising a vacuum station, an enclosure, a cutter and a motor, wherein 'movement of said cutting element assembly through said aperture causes said shield to move to said second position, and wherein movement of said cutting element assembly from

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said deployed position to said home position causes said shield to move from said second position to said first position covering said aperture'. As was pointed out in the 10/04/2007 Office Action, it is not clear what structural elements would provide for the recited functionality. In particular, the claim does not set forth what elements would link the movement of the cutting element assembly through the aperture to the movement of the shield to the second position, and the movement of the cutting element assembly from the deployed position to the home position to the movement of the shield from the second position to the first position. It is also unclear whether or not any controller is intended. It appears that the recited functionality is not possible without a controlling device. See also claim 4. Additionally, it is not clear what structural elements would provide for the sample testing. Thus, the instant claims are incomplete for omitting essential elements. See MPEP § 2172.01.

***Claim Rejections - 35 USC § 102***

5. The 35 U.S.C. § 102(b) rejection of claims 1, 3 and 10 as being anticipated by Krainer et al. (US 5471016), has been withdrawn, in light of the latest amendments.

***Claim Rejections - 35 USC § 103***

6. Claims 1-4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karl et al. (US 5891396) in view of Wirtz-Odenthal (US 5161723).

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Karl et al. disclose an automatic sample testing machine for testing samples comprising a vacuum station for loading fluid samples (see Abstract) and a cutting and sealing station (illustrated in Figures 4-5) which includes a hot cutting wire 506 attached to a support plate 504 and connected to a stepper motor drive mechanism 502. The wire assembly is movable between a lower position, at the level of transfer tubes 32 ['deployed position'] and an upper ['home'] position – (see Col.7, lines 45 plus).

Although the upper portion of the center mount 34, along with the wall structures of the machine 20 appear to form a kind of a bottom open enclosure, Karl does not specifically teach an enclosure and a shield covering an opening in the enclosure.

Wirtz-Odenthal discloses a foil dispenser “having a housing with an outlet opening adjacent which an electrically heatable wire functions as a foil cutter. The wire normally is covered by a plate-like drop shutter ['shield having two positions' – Ex.] so that the user...will not get his fingers burnt easily by the wire' (Col.1, lines 21-27). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have arranged an enclosure with a shield around the hot wire in the modified apparatus of Karl, in order to protect an operator.

Referring to claim 4, Karl discloses a sample card transport station 700 which includes a drive assembly 702 comprising biasing springs 714 (Figure 17). It appears that, in a similar manner, the drive mechanism 502 connected to

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the cutting wire 506 via support plate 504 ['spring loaded member'], must also comprise biasing springs. It would have been also within the ordinary skill of an artisan to have employed such springs in the modified apparatus of Karl, in order to provide more reliable connection between the working elements of the sealing and cutting station.

### ***Response to Arguments***

7. Applicant's arguments dated 01/10/2008 have been fully considered but they are not persuasive, or moot in view of new grounds of rejection.

Applicant argues that, by rejecting the instant claims under 35 U.S.C. 112, second paragraph, the 'Examiner is seeking to impose undue narrowing to the claim'. Examiner maintains that the missing structural elements (see the discussion above) render the claims incomplete and, therefore, unclear.

Applicant argues that the particular manner in which the functionality occurs, 'need not be recited in the claim. Examiner agrees with this argument, and notes that the rejection pertains not to the manner, but to the missing important structural features (see above).

Applicant argues that 'If the Examiner's logic was applied across the board, no broadly drafted claim would ever be allowable, nor would a claim which uses functional language ever be allowed. Functional language, as used in this claim, does not necessarily render a claim improper or indefinite'. Examiner agrees and maintains that the rejection deals with the structural gaps (see above).

Applicant argues that Wirtz-Odenthal does not suggest a cutting element 'which includes a motor that moves the cutting element through the opening and moves the shield to the second (retracted position)'. Examiner would like to remind that Wirtz-Odenthal was cited to support the statement that it would have been within the ordinary skill of an artisan art at the time the invention was made to have arranged an enclosure with a shield around the hot wire in the modified apparatus of Karl, in order to provide additional protection.

Applicant argues that 'there is nothing in Karl that would suggest that the sealer in Karl should be modified to have the enclosure and shield features', since Karl et al. instrument is a completely automated instrument, and once a tray loaded with test devices is placed in the Karl instrument, the processing operations (including sealing operation) occur without any human involvement'. Examiner notes that even the highest level of automation does not preclude, but, on the contrary, requires additional protective means to provide 'fool-proof' security.

Applicant argues that 'nothing in Karl suggests incorporating the claimed spring-loaded member into the sealing station of Karl'. Examiner maintains that, Karl discloses a sample card transport station 700 which includes a drive assembly 702 comprising biasing springs 714 (Figure 17). It appears that, in a similar manner, the drive mechanism 502 connected to the cutting wire 506 via support plate 504 ['spring loaded member'], must also comprise biasing springs. It would have been also within the ordinary skill of an artisan to have employed

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such springs in the modified apparatus of Karl, in order to provide more reliable connection between the working elements of the sealing and cutting station.

Applicant argues that 'claim 1 recites that "wherein movement of said cutting element assembly through said aperture causes said shield to move to said second position, and wherein movement of said cutting assembly from said deployed position to said home position causes said shield to move from said second position to said first position covering said aperture... ". This is not the case in Macgrory. The action which moves the shield ("drop plate" 34) in Macgrory is the action of pulling and lifting up of the sheet of film, not movement of the hot cutting wire. The hot cutting wire in Macgrory does not move or cause the drop plate to open'. Examiner notes that Macgrory was not cited by the Examiner in the rejection.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory

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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797